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Document Title	REPORT TO DOW CORNING CORPORATION SKIN IRRITATION STUDIES ON TWO MATERIALS (TX-46C AND TX-47A) WITH COVER LETTER DATED 042094		
Chemical Category	SILOXANES AND SILICONES, DI-ME (63148-62-9)		

OFFICE OF TOXIC SUBSTANCES
CODING FORM FOR GLOBAL INDEXING

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OFFICE OF PREVENTION,
POLLUTION AND TOXIC
SUBSTANCES

April 20, 1994

TSCA Document Processing Center (TS-790)
Office of Prevention, Pollution and Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460
Attn: 8(d) Health and Safety Data Reporting Rule

Re: 58 FR 28511 (May 14, 1993) [OPPTS-82040; FRL-4182-1]
Health and Safety Data Reporting; 40 CFR Part 716
ITC 30-Listed Siloxanes and Silicones

Dear Sir:

The enclosed information is submitted on behalf of Dow Corning Corporation, Midland, Michigan, 48686-0994, in compliance with the referenced health and safety data reporting rule.

Listed Chemical Substance(s):

63148-62-9 Siloxanes and silicones, di-Me (Dimethyl
silicones and siloxanes) identified as
TX-46C

Title of Submitted Study:

REPORT TO DOW CORNING CORPORATION SKIN IRRITATION STUDIES ON
TWO MATERIALS

Dow Corning Corporation
October 2, 1964

Manufacturer:

Dow Corning Corporation
2200 West Salzburg Road
Midland, MI 48686-0994

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If you require further general information concerning this submission, please contact Dr. Rhys G. Daniels at 517-496-4222. For further information concerning the submitted study or the toxicological properties of the listed chemical substance, please contact Dr. Robert G. Meeks at 517-496-8629.

Sincerely,

Alvin E. Bey

Alvin E. Bey
U.S. Area Vice-President
Corporate Director HES

Industrial BIO-TEST Laboratories, Inc.

1510 FRONTAGE ROAD

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ORIGINAL REPORT

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REPORT TO
DOW CORNING CORPORATION
SKIN IRRITATION STUDIES ON
TWO MATERIALS

RECEIVED
OCT 14 1964

DOW CORNING CORPORATION
ANALYTICAL DEPT.

1964-10065-105

REPORT TO
DOW CORNING CORPORATION
SKIN IRRITATION STUDIES ON
TWO MATERIALS

I. Introduction

Two samples identified as TX-46C and TX-47A were received from Dow Corning Corporation for the purpose of conducting skin irritation studies using albino rabbits as test animals.

II. Procedure

The procedure followed in the evaluation of each material was the same and is described below.

Four albino rabbits were used in the evaluation of primary skin irritating properties of the test material. The test procedure employed was modeled after that of Draize et al*.

Prior to the application of the test material, the hair was clipped from the backs and flanks of each of the four rabbits. Two test sites located at the midline of the back approximately ten centimeters apart

* "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes", Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., J. Pharm. & Exp. Ther., 82, 4, December 1944.

were selected on each rabbit. One of the two sites selected was abraded by making four epidermal incisions, two perpendicular to the other two while the other skin site remained intact.

The test material was applied undiluted to the skin of the prepared exposure sites on each of four rabbits. Applications were in the form of square gauze patches, 2.5 cm on a side, containing 0.5 ml of undiluted test material. These were affixed directly over the skin test sites and secured in place by means of thin strips of adhesive tape.

In the above manner, the test material was evaluated for primary irritation on each of four rabbits, a total of eight sites (four intact and four abraded) being employed.

Following the patch applications, the entire trunk of each test animal was wrapped in an impervious plastic sheeting. This helped to hold the patches in position and retarded evaporation during the 24-hour exposure period.

At the end of 24 hours, the plastic wrappings and patches were removed. The skin sites were then individually examined and scored separately for both erythema and edema on a graded scale of 0 to 4. After 72 hours had elapsed, the sites were re-examined and rescored.

In evaluating the average irritation present, scores for individual intact and abraded sites were recorded separately for each of the two scoring time intervals. The mean scores for the 24- and 72-hour grading periods were then averaged to obtain separate mean irritation grades for

both intact and abraded skin. Finally, the latter two means were averaged to give a combined average irritation score. The scoring criteria for erythema and edema are shown in Table I.

TABLE I

Scoring Criteria for Skin Reactions

Erythema and Eschar Formation

Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Total Possible Erythema Score	4

Edema Formation

Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Total Possible Edema Score	4

Total Possible Primary Irritation Score	8
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III. Results

The skin irritation scores and ratings are presented in Tables II and III.

TABLE II

TEST MATERIAL: TX-46C

Primary Skin Irritation

Results

Animal Number	Intact Skin		Abraded Skin		Combined Average
	24 Hours	72 Hours	24 Hours	72 Hours	
1	2.0	1.0	2.0	1.0	
2	4.0	1.0	4.0	1.0	
3	2.0	1.0	4.0	1.0	
4	3.0	1.0	4.0	1.0	
Mean	1.9		2.2		2.0

Primary Irritation Rating: Mildly Irritating

TABLE III

TEST MATERIAL: TX-47A

Primary Skin Irritation

Results

Animal Number	Intact Skin		Abraded Skin		Combined Average
	24 Hours	72 Hours	24 Hours	72 Hours	
1	2.0	1.0	2.0	1.0	
2	2.0	1.0	2.0	1.0	
3	3.0	1.0	3.0	1.0	
4	4.0	1.0	4.0	1.0	
Mean	1.9		1.9		1.9

Primary Irritation Rating: Mildly Irritating

IV. Summary

The results of skin irritation studies conducted on samples TX-46C and TX-47A revealed that both test materials were mildly irritating to the intact and abraded skin of albino rabbits.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Richard J. Palazzolo
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Associate Director

J. C. Calandra
J. C. Calandra, M.D., Ph.D.
Director

October 2, 1964



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